



Technology: 7 significant changes under the impending PHS conflict of interest rule

The rule aims to increase oversight of relationships between industry sponsors and academic researchers

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In August 2011, the federal Department of Health and Human Services released a final rule that updates the regulations governing conflicts of interest in research supported by, or proposed to be supported by, the Public Health Service (PHS). The new rule updates regulations that have been in place since 1995 and covers, among other research, that funded by the National Institutes of Health. Like the Physician Payments Sunshine Act, the new PHS conflict of interest rule aims to strengthen accountability, enhance transparency and increase governmental compliance oversight in light of the growth in biomedical research and the increasingly complex nature of relationships between industry sponsors and academic researchers. Institutions must comply with the new rule by Aug. 24, 2012.

Significant changes under the new conflict of interest rule include the following:

1. Broadening the scope of individuals who are required to disclose financial interests to institutions to include not only the designated principal investigator but also anyone, regardless of title or position, who is responsible for the design, conduct or reporting of research, including consultants and collaborators
2. Lowering the minimum threshold at which an individual must make disclosures of significant financial interests from \$10,000 to any equity interest in a non-publicly traded entity, regardless of value, and to \$5,000 for any other financial interests
3. Expanding the scope of financial interests to be reported by investigators from only those related to the PHS-funded research, as determined by the investigator, to those related to any of the investigator's institutional responsibilities
4. Requiring institutions to determine whether a reported significant financial interest is related to the PHS-funded research and whether it could directly and significantly affect the design, conduct or reporting of the PHS-funded research and thus constitute a financial conflict of interest
5. Requiring institutions to report to the PHS not only the existence of a financial conflict of interest but also detailed information about the nature and value of the financial interest, the

name of the entity with which the investigator has a conflict and a description of the institution's management plan for the conflict

6. Requiring institutions to make certain information about financial conflicts of interest publicly available via a website or by providing written information within five business days after receiving a request, with such information to include the investigator's name and role in the research project, the name of the entity in which the investigator holds a financial interest and the nature and approximate dollar value of the significant financial interest
7. Requiring institutions with policies that are more stringent than the PHS requirements to follow their policies and to provide reports in accordance with them

The new rule significantly expands institutions' responsibilities with respect to reviewing significant financial interests of investigators, reporting conflicts of interest to the PHS and making information available to the public. However, whether these changes enhance the objectivity of PHS-funded research and result in increasing public trust in research and medicine, as the PHS intends, remains to be seen. In particular, the new rule raises the following questions, among others:

- How should institutions handle institutional conflicts of interest?

In commentary accompanying the new rule, the PHS mentions that it considered requiring institutions to adopt policies on institutional conflicts of interest. However, the PHS did not, and institutional conflicts remain unregulated. Relationships between industry sponsors and institutions have grown more common in recent years, and leaving it up to institutions themselves to handle the effects of these relationships on research could lead to significant gaps in the recognition and management of conflicts of interest.

- What will be the effect of institutions' public disclosure of investigators' financial conflicts of interest?

As with the Physician Payment Sunshine Act and other disclosure laws, how the disclosed information will be used by the public and whether the information will prove helpful in understanding the effect of the

financial interests on the research are not clear. In particular, under the new PHS rule, an institution must make the basic facts surrounding an investigator's financial conflict of interest publicly available, but it is not required to explain its plan for managing the conflict. The disclosed information may raise more questions in the mind of the public than it answers

In light of these outstanding issues, institutions should focus not only on the operational details necessary to comply with the new PHS rule but also on broader issues surrounding their research activities and relationships with industry sponsors, including perceptions, both within the institution and beyond, about their objectivity in conducting research.